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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/226,597 01/07/99 PIMENTEL

J 585-017-84

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| EXAMINER |
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| GABEL, G | |
| ART UNIT | PAPER NUMBER |

1641

DATE MAILED:

02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/226,597

Applicant(s)

PIMENTEL, JULIO

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 17) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Request for Reconsideration

1. Applicant's response filed 12/5/00 in Paper No. 9 is acknowledged and has been entered. Currently, claims 1-9 are pending and under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,919,451) in view of Leclercq et al. (Reproduction, Nutrition, and Development, 1990) for reasons of record.

Response to Arguments

3. a) Applicant contends that the present invention relates to "a method of decreasing the amount of body weight normally gained after eating" by feeding it an effective amount of an antibody that binds to the enzyme lipase.

In response, the feature upon which applicant relies, i.e. "a method of decreasing the amount of body weight normally gained after eating" is not distinctly recited in the

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rejected claims. Specifically, the preamble in claim 1 recites "a method for inhibiting body weight gain" (by feeding...). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

b) Applicant argues that Cook et al. discloses an animal feed containing antibodies that can alter physiological processes and did not disclose antibodies that bind lipase. Applicant argues that Leclercq et al. discloses an anti-lipase antibody but does not use the antibody to inhibit fat absorption or digestion in the gut (oral administration) but rather to inhibit fat metabolism into cells with the purpose of changing body composition (injection). Applicant, therefore, contends that the combination of Cook and Leclercq does not teach or suggest the present invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837

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F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Cook et al. disclose feeding an animal a food composition that contains antibodies which can alter physiological processes that affect growth (regulate/inhibit growth of an animal) or improve feed efficiency of the animal to convert its feed into desirable lean body tissue wherein the food composition is optionally liposome-encapsulated. Such antibodies can be specific endogenous regulators of digestion (food intake) or gastrointestinal mobility. Leclercq et al. has been incorporated thereto for his teaching of the capacity of antilipase antibodies to affect metabolism by inhibiting adipose activity and reducing fat accumulation in cells; thereby, inhibiting body weight gain" (by feeding...). One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in substituting antilipase antibodies such as taught by Leclercq, into the liposome-encapsulated antibodies in the animal feed of Cook because Cook taught that any antibody that can alter physiological processes, i.e. inhibition of fat absorption such as those taught by Leclercq, can be incorporated into his feed. Physiological processes as suggested by Cook encompass digestion, absorption, or metabolic activity. One of ordinary skill in the art would have been motivated to incorporate the teachings of Leclercq into the method and food composition of Cook because Cook taught that his method provides advantage in large scale applications and wide variety of purposes for providing an easy and convenient mode of delivering antibodies that alter physiological processes and affect growth,

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health, weight, and feed efficiency of large population of animals such as those produced and raised for consumption.

c) Applicant argues that Cook et al. did not suggest encapsulating the antibodies with true liposomes, but rather with lipid layer.

In response, Cook et al., indeed, suggested optionally encapsulating the antibodies with liposomes. Liposomes are defined as "microscopic vesicles consisting of an aqueous core enclosed in **one or more phospholipid layers**, used to convey vaccines (antibodies), drugs, enzymes, or other substances **to organs or target cells**" (CancerWEB's On-line Dictionary- attached).

4. Applicant's arguments filed 12/5/00 have been fully considered but they are not persuasive. Accordingly, no claims are allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

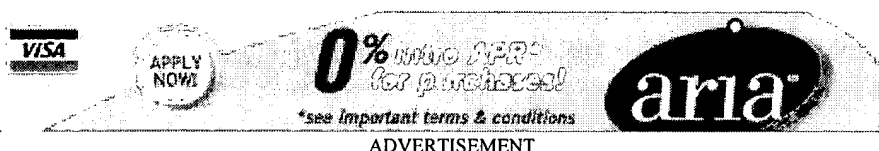
 2/23/01

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02/26/01

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lip·o·some (lɪp'ə-səm', lɪ'pə-)
n.

An artificial microscopic vesicle consisting of an aqueous core enclosed in one or more phospholipid layers, used to convey vaccines, drugs, enzymes, or other substances to target cells or organs.

lip'o·so'mal *adj.*

Pronunciation Key

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liposome

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